



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

#37

JUN 3 1996

Paul Grandinetti
LEVY, ZITO & GRANDINETTI
1725 K Street, N.W. Suite 1401
Washington, D.C. 20006-1401

Re: Patent Term Extension
Application for
U.S. Patent No. 4,735,621

The application for patent term extension for U.S. Patent No. 4,735,621 which claims the medical device REALITY Female Condom, has been reviewed in view of the decision of the Court of Appeals for the Federal Circuit in Merck & Co. v. Kessler, 38 USPQ2d 1347 (1996). In view of this decision, the application for patent term extension must be dismissed as moot since the period of extension would extend the term of the patent from its 20-year expiration date instead of the 17-year expiration date.

U.S. Patent No. 4,735,621 issued April 5, 1988 from an application that was filed on June 5, 1987. The length of the extension which may be granted for a patent eligible for extension cannot exceed fourteen years for the date of approval of the approved product. 35 U.S.C. § 156(c)(3). Under the circumstances of this application for patent term extension, the twenty-year term of the subject patent (due to expire June 5, 2007) will not expire until almost a month after the critical limit for an extension of fourteen years from the approval date (i.e. May 7, 2007). Even though the subject patent may meet all of the requirements of eligibility for patent term restoration under 35 U.S.C. § 156(a), the application fails to provide a prima facie showing that the term of U.S. Patent No. 4,735,621 could be extended under 35 U.S.C. § 156.

The application for patent term extension is dismissed as moot.

Hiram A. Bernstein
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fisher's Lane, Room 11-44
Rockville, MD 20857

RE: REALITY
FDA Docket No.: 93E-0290